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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/764,050	01/19/2001	Tadashi Okamoto	35.C15261	6689

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FITZPATRICK CELLA HARPER & SCINTO
30 ROCKEFELLER PLAZA
NEW YORK, NY 10112

EXAMINER

TUNG, JOYCE

ART UNIT	PAPER NUMBER
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1637

DATE MAILED: 04/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

811

Office Action Summary

Application No.

09/764,050

Applicant(s)

OKAMOTO ET AL.

Examiner

Joyce Tung

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 December 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>12312003</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The applicant's Response (December 23, 2003) has been entered. Claims 1-26 are pending. Rejections and/or objected from the previous office action are hereby withdrawn. The following rejections are either newly applied or reiterated. They constitute the complete set presently being applied to the instant application.

Information Disclosure Statement

1. The reference in the 1449 filed December 31, 2003 has not been considered because there is no English translation for the reference. It is suggested to provide English translation for the reference.

2. Claims 1-9, 11-15, 18, 20-22 and 25 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Sutherland et al. (WO 87/06956) in view of Johann et al. (6,277,628).

Sutherland et al. Disclose a waveguide coated with single-stranded probe nucleic acid in which the single-stranded sample nucleic acid is allowed to react with the probe in the presence of intercalant fluorescence dyes (See pg. 5, fifth paragraph). An analyte solution contains test DNA or RNA (See the Abstract). A double stranded DNA is used with ethidium bromide (See pg. 36, third paragraph). The waveguide substance is a plastic cuvette (See pg. 40, claim 14.

Sutherland et al. do not disclose drying the hybrid and the fluorescence dye on the substrate.

Johann et al. disclose a method and a composition for detecting the levels of a plurality of biomolecular probes in a sample. In particular the invention relates to a hybridization composition for detecting the presence or the levels of different polynucleotide sequences in a sample (See the Abstract). The biomolecular probe comprises polynucleotide probes and the targets are complementary to the polynucleotide sequences (See column 1, lines 55-57) in which target is immobilized (See column 1, lines 45-48). The target can be DNA or RNA (See column

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5, lines 20-36). The labels can be fluorescent markers and dyes (See column 5, lines 37-48). The labeling moiety can be incorporated after hybridization once a probe-target complex is formed (See column 5, lines 49-53). The Cy5-5' labeled 59mer was used to fill a glass bead capillary array. The array was washed and then dried and scanned with a confocal fluorescence microscope (See column 8, lines 22-32).

One of ordinary skill in the art at the time of the instant invention would have been motivated to apply the drying step of Johann et al. (See column 8, lines 22-32) to the method of Sutherland et al. because with the drying step, the method of Johann et al. is high throughput hybridization experiments utilizing small sample as desired (See column 2, lines 32-35). Thus, it would have been prima facie obvious to apply Johann et al. drying step to Sutherland et al.'s detection assay in order to carry out the claimed method.

The response argues that one ordinary skill in the art would not have been motivated to apply the drying step of Johann to Sutherland because Sutherland teaches away from the use of extra manipulations in which applying the drying step of Johann is considered to use extra manipulation as addressed in the response. It is true that the method of Sutherland is to avoid many of the skilled manipulation associated with current techniques (See pg. 5, third paragraph). However, Sutherland does not specifically indicate what step is the manipulation. Therefore, the argument has been fully considered, but it is not found persuasive. The rejection is maintained.

3. Since there is no specific argument regarding applying the references of Miyakoshi and Yamamoto, the rejections are maintained and restate as follows.

4. Claim 10 remains rejected under 35 U.S.C. 103(a) as being unpatentable over Sutherland et al. (WO 87/06956), in view of Johann et al. (6,277,628) as applied to claims 1-9, 11-14, 18, 20-21 and 25 above, and further in view of Miyakoshi et al. (JP404330300).

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The teachings of Sutherland et al., and Johann et al. are set forth in section 2 above and Sutherland et al. and Johann et al. do not disclose using resin as solid-phase substrate as claimed in claim 10.

Miyakoshi et al. disclose that a resin membrane is used to efficiently immobilize a short-chain nucleic acid, thus simplifies operation of hybridization (See the Abstract).

Thus, one of ordinary skill in the art at the time of the instant invention would have been motivated to apply resin membrane as solid phase substrate because a resin membrane was used to efficiently immobilize a short-chain nucleic acid, thus simplifies operation of hybridization (See the Abstract). It would have been prima facies obvious to apply resin membrane as solid phase substrate as claimed.

5. Claims 16, 17, 19, 23-24 and 26 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Sutherland et al. (WO 87/06956), in view of Johann et al. (6,277,628) as applied to claims 1-9, 11-15, 18, 20-22 and 25 above, and further in view of Yamamoto et al. (Nucleic Acid Research, 1995, Vol. 23(8), pg. 1445-1446).

The teachings of Sutherland et al. and Johann et al. are set forth in section 2 above and Sutherland et al. and Johann et al. do not disclose using pyrylium salt and YOYO-1 as intercalator as claimed in claims 16, 17, 19, 23-24 and 26.

Yamamoto et al. disclose a new method of detecting the nucleic acid amplified products using a fluorescent intercalator pyrylium salt (P2) which shows strong fluorescence when reacted with double stranded DNA(dsDNA) in proportion to the amount of dsDNA (See pg. 1445, third paragraph). YOYO-1 has also a large increase of fluorescence intensity when it is intercalated into dsDNA (See pg. 1446, second paragraph).

Thus, one of ordinary skill in the art at the time of the instant invention would have been motivated to apply the fluorescence intercalator of Yamamoto et al. to the method of Sutherland et al. because of the benefit of using the fluorescent intercalator pyrylium salt (P2) and YOYO-

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1 as discussed above. It would have been prima facie to use a fluorescent intercalator pyrylium salt (P2) and YOYO-1.

Summary

6. No claims are allowable.

Conclusion

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

8. Any inquiries concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is (571) 272-0790. The examiner can normally be reached on Monday-Friday from 8:00 AM-4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached at (571) 272-0790 on Monday-Friday from 10:00 AM-6:00 PM.


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Any inquiries of a general nature or relating to the status of this application should be directed to the Chemical/Matrix receptionist whose telephone number is (703) 308-0196.

9. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Art Unit 1637 via the PTO Fax Center located in Crystal Mall 1 using (703) 305-3014 or 308-4242. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Joyce Tung

^{S.T.}
March 23, 2004


KENNETH R. HORLICK, PH.D
PRIMARY EXAMINER

4/1/04